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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,600	07/28/2000	Samuel R. Demmeade	07265-191001	3631

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/627,600	DENMEADE ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendment filed 19 February 2002, which amends claims 8, 28 and 29 has been entered. The following Office action is applicable to the pending claims 1-62.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 60-62, drawn to a peptide having a proteolytic activity of human Kallikrein 2 (hk2), are classified in class 530, subclasses 300, 350 and 407.

II. Claim 15, drawn to a peptide composition comprising a plurality of peptides, each peptide comprising a peptide sequence having a specific cleavage site for an enzyme having hk2 activity, is classified in class 514, subclass 2, and class 530, subclasses 300 and 350.

III. Claim 16, drawn to a polynucleotide encoding the peptide of Group I, is classified in class 536, subclass 23.1, class 435, subclass 440.

IV. Claims 17-56, drawn to a drug composition comprising a therapeutic drug and the peptide of Group I wherein the peptide is linked to drug, and a method of making said composition, are classified in class 514, subclass 2, and class 530, subclasses 378.3, 300 and 350.

V. Claim 57, drawn to a method of selecting a prodrug that activates hk2 protein (enzyme) comprising (i) linking the peptide of Group I to a drug, (ii) contacting the composition comprising the peptide-drug conjugate produced by step *i* with target cells,, (iii) contacting the said composition with non-target cells, and (iv) selecting complexes formed between the composition and the target cells wherein the complexes are toxic toward the target cells, is classified in class 514, subclass 2, and class 424, subclass 9.6.

VI. Claim 58, drawn to a method of determining hk2 activity in a sample comprising (i) contacting the sample with a composition comprising labeled peptide, (ii) detecting labeled level, and (iii) comparing the detected level with a standard hk2 sample, is classified in class 514, subclass 2, and class 424, subclass 9.6.

VII. Claim 59, drawn to a method of imaging a tissue producing hk2 comprising (i) administering a peptide of Group I that is linked to a lipophilic imaging label to a subject, (ii) allowing cleavage of said peptide by the hk2 enzyme and imaging the subject, is classified in class 514, subclass subclass 2, and class 424, subclass 9.6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are patentably distinct from each other because of the materially different structures of the compounds claimed. The Invention III is drawn to polynucleotide while Invention I to polypeptide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Invention II and invention I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because 1) the utility of a peptide composition does not necessary depend on the utility of each separate peptide in the composition, and 2) each peptide in said composition of Invention II has utility by itself, e.g., acts as a binding ligand or epitope for immunogenicity.

Invention IV and invention I are also related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because 1) the utility of a drug composition does not necessary depend on the utility of each separate peptide, which is linked to the drug in the composition, and 2) each drug moiety in said composition of Invention IV has utility by itself, e.g., for treating a disease state.

Inventions V, VI, and VII and invention III are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Invention II and III since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Invention I relates to Inventions V-VII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide can be used to raise an antibody, for example.

Invention II are unrelated to Inventions V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the peptide composition can be coated on a gold-surface in surface plasma resonance technology for studying a real-time protein-protein interaction.

Invention III are unrelated to Inventions V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide of Invention III can be used in hybridization or in DNA-array technology.

Invention IV and Inventions V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition comprising the peptide can be used to raise an antibody, for example.

Invention IV are unrelated to Invention VI because Invention VI uses the composition comprising a labeled peptide which is distinct from the peptide in Invention IV, wherein the peptide is covalently linked to a therapeutic drug. Also, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the composition of Invention IV can be immobilized on a gold-surface in surface plasma resonance technology for studying a real-time protein-protein interaction.

Invention IV are unrelated to Invention VII because Invention VII uses the composition comprising imaging labeled peptide which is distinct from the peptide in Invention IV, wherein the peptide is covalently linked to a therapeutic drug. Also, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the composition of

Invention IV can be used as an immunogenic epitope for imaging an immunological reaction.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Samuel Wei Liu, Ph.D.
June 23, 2004

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER